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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,584	06/19/2003	Robert W. Blakesley	55670DIV(45858)	5497

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EXAMINER

BABIC, CHRISTOPHER M

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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09/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/600,584	Applicant(s) BLAKESLEY ET AL.	
	Examiner CHRISTOPHER M. BABIC	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,27,33-37 and 39-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,27,33-37 and 39-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/7/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 7, 2009 has been entered. Claim(s) 26, 27, 33-37, and 39-48 are pending and under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26, 27, 33-37, and 39-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. ("Bacterial typing: storing and processing of stabilized reference bacteria for polymerase chain reaction without preparing DNA--an example of an automatable procedure" Anal Biochem. 1997 May 1;247(2):223-7) in view of Burgoyne (U.S. 5,496,562), and in view of Kahn et al. (Plasmid cloning vehicles derived from plasmids ColE1, F, R6K, and RK2" Methods Enzymol. 1979;68:268-80).

The claims are drawn to a method of isolation of vectors from host cells by contacting the host cells with a solid medium. In some embodiments the solid medium protects the vector from degradation, is made of cellulose or a micromesh plastic, the host cells are in solution, and the solid medium comprises urate salt, a chelating agent, and an anionic detergent.

Rogers et al. shows in the abstract and throughout recovery of DNA from bacterial liquid cultures by application of the bacterial culture to FTA® blood storage medium. Figures 1 and 2 show positive results of PCR assay of bacterial DNA from FTA® media to which bacterial cultures were applied. Rogers et al. shows that the DNA is stable for at least 1.6 years after application to the FTA® media on page 226. Rogers et al. does not show use of bacteria comprising vectors, media comprising micromesh

plastic, and Rogers et al. does not detail the composition of the chemicals in the FTA media. Rogers et al. states on page 223 that FTA® medium is described in Burgoyne (U.S. Patent No. 5,496,562).

Burgoyne shows the components of a solid medium for preserving DNA from blood cells in columns 2-4, including use of a solid support such as cellulose or a micromesh of a synthetic plastic (column 2, lines 21-23), urate, an anionic detergent, and a chelating agent (column 2, lines 54-64 and column 3, lines 18-26). Burgoyne shows the application and storage of isolated plasmids on the solid medium in Example 2, columns 4-6. Burgoyne discloses application of plasmid pUC19 and recovery of approximately 100% of the applied plasmid from the solid matrix in column 6. Burgoyne claims a method of application of generic DNA and recovery of the applied DNA from a solid matrix in at least claim 6.

Kahn et al. reviews plasmid cloning vectors, and shows that such vectors are replicated in bacteria in the abstract and throughout. Kahn et al. shows on page 268 that plasmid vectors are useful for cloning and maintenance of foreign DNA.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Rogers et al. by use of bacteria comprising vectors because Burgoyne shows that the solid media used by Rogers et al. can be used for long term storage and recovery of plasmids, and Kahn et al. shows that bacterial plasmid vectors are useful for cloning and maintenance of foreign DNA.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

As understood by the examiner, Applicant is asserting that it would have been unexpected to one of ordinary skill in the art at the time of invention to find that the recovery plasmid DNA from the claimed solid phase was possible in the presence of genomic DNA, particularly given the amount low copy number of some plasmids. First it is noted that the claim does not require a particular plasmid copy number. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, Applicant provides no objective evidence of probative value in support of the "unexpected" results. While the examiner must consider all rebuttal arguments and evidence presented by Applicant including "secondary considerations" such as unexpected results, such a showing of unexpected results must be based on evidence, not argument or speculation. *In re Mayne*, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997) (see MPEP 2145). The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) (see MPEP 2145). Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations

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that the author(s) of the prior art derived the disclosed subject matter from the applicant.

See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) (see MPEP 716.01(c)).

Thus, the rejection is maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 814-880-9945. The examiner can normally be reached on Monday-Friday 10:00AM to 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Primary Examiner
Art Unit 1637
Technology Center 1600